The Manitoba Pharmaceutical Association

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The Submission of the Manitoba Pharmaceutical Association To the Task Force on Drug Importation As created by the Health and Human Services Secretary, Tommy G. Thompson

April 27, 2004

To: Richard H. Carmona, M.D., M.P.H., F.A.C.S.
VADM, USPHS
United States Surgeon General
Chairman, Secretary's Task Force on Importation
Department of Health and Human Services
Food and Drug Administration Building
Conference Room 1031
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The Manitoba Pharmaceutical Association (M.Ph.A.) is the pharmacy licensing authority pursuant to the provincial *Pharmaceutical Act*, in Manitoba, Canada. The principal mandate of the self-regulating authority of M.Ph.A. is the protection of the public. This provides a wide scope of responsibilities that include licensure, establishing and auditing compliance of standards, complaint investigations, public and professional relations, and, liaison and advisory with the public, different levels of provincial and federal governments and industry. The M.Ph.A is a founding member of Canada's National Association of Pharmacy Regulatory Authorities (NAPRA) and is a member of District Five, National Association of Boards of Pharmacy (NABP). The M.Ph.A. was first formed in February 1878 and celebrated the 125th anniversary in 2003.

The list of preliminary questions proposed by Dr. Richard Carmona was reviewed and it is an impossible task for one organization to be knowledgeable and be able to address all the issues raised. However, the M.Ph.A. does have expert knowledge in certain areas of this cross-border legal drug activity. We hope to provide some insight as well as to learn from our attendance at the Task Force meeting.

Clearly, there are two major issues of concern in any drug delivery system whether it is within an institution, across town, across state or across international borders. The two

issues are patient safety, and, product quality and safety. Those two issues are a common theme through most of the questions posed by Dr. Carmona.

Prior to the year 2000, it was difficult for pharmacies located in Canada to send medications into the United States. It was not possible for American patients wanting to purchase medications from Canada as the American customs officials would reject the entry of the packages. This led to private and state run "drug bus tours" to Canada for the purchase of prescription medications. For Canadian patients temporarily residing in the United States, the pharmacies had to include documentation that the medication was legally prescribed and dispensed for a Canadian temporarily residing in the United States. Even with medication declared and the informed enclosed, the medication could be refused entry into the United States. Sometime in late 2000, the level and policy of enforcement changed. The changes was noted by our Field Operations and reported to the Council of The Manitoba Pharmaceutical Association.

The shipping of medication from Canada to the United States was first declared "Internet Pharmacy" and left the impression of enhanced utilization of technology to deliver care. Clearly, the internet was just a form of advertising to reach a broader audience and this "industry" was no more "high tech" than mail-order pharmacy. For the most part, that has not changed. First contacts with the federal Food and Drug Administration left the M.Ph.A. with the impression that there was not going to be a return to the pre-2000 activity of refusing entry of Canadian medication for American use. This caused the Council of M.Ph.A. to be proactive and to develop standards of practice around this new found "industry". A combination of very aggressive business people located in Manitoba, support by the government of Manitoba and the standards developed to make sure this "industry" focused on patient care caused Manitoba to become the center of "internet pharmacy". The name applied to pharmacies sending medication into the United States is International Prescription Service (IPS) Pharmacies and it required an additional fee and declaration on their 2003 pharmacy license application.

What may have started with a few "internet savvy" seniors citizens purchasing medications that they desperately needed and willingness to take a chance on their pharmacy neighbors to the north, quickly developed into a multi-billion dollar industry. Now, however, this industry involves new concepts in the drug delivery system namely "prescription brokers, pharmacy affiliates, prescription co-signers, fulfillment centers and international prescription service pharmacies". The M.Ph.A.'s intention to ensure that the drug delivery system was safe and focused on patient care has developed into a fulltime and mostly legal joust between the M.Ph.A. and some of the International Prescription Services (IPS) Pharmacies. The challenge for the M.Ph.A. to insure patient safety and product quality continues and much more work has to be done. There has been an attitudinal shift from a sector within the pharmacy profession to go no further than the letter of the law and develop legal arguments and controversy regarding the spirit and professional intent of the law.

It is not possible for any one province or state regulatory agency to possess sufficient expertise and resources to ensure patient and product quality and safety beyond the

geographic borders of their jurisdiction. The M Ph.A has received a legal opinion that all patients who receive medication and care from Manitoba pharmacies are part of the "public" and are protected as if they were Manitobans. Notwithstanding M.Ph.A. substantially increased fees to IPS Pharmacies in 2003, the expertise and resources are insufficient.

The M.Ph.A. can assure the Task Force that the safety assurances placed on products by Health Canada would extend for use by Americans. The M.Ph.A. can also assure the Task Force that Manitoba pharmacists are of equivalent competency to American pharmacists regarding knowledge, patient orientated care and standards of practice. However, this "industry" has a certain amount of "gold rush mentality" and "frontierism" that can, and does, make it dangerous. The regulatory authorities, in every province and state, need additional powers, resources and expertise to make sure the focus remains, as described earlier, patient safety and product quality and safety.

There is no question that the Canadian drug supply system cannot supply the all needs of American patients. The health care system in Canada has been affected through real or artificially created drug shortages, increased drug prices and increased costs in the delivery of health care services. In addition, there strong concern that new and/or innovative products will not be introduced into the Canadian market. As a result, this industry has already begun to cause harm to the Canadian medication consumer. Notwithstanding, there is an expressed commercial need for this industry to continue within some areas of Canada.

Presuming for a moment that all parties wish the cross-border movement of drugs to continue and continue to grow and may result in the movement of medications in both directions across the Canada/United States border, it is vitally important that the two basic issues are clearly identified, addressed and enforced. Therefore, before any activity to consider legalizing, condoning and enhancing the cross-border movement of prescription and non-prescription (legal) drugs occurs on either side of the international border, the following points need to be addressed:

1. The development of international standards and agreements that confirm and enforce patient care as the primary goal and placed above the commercial interests for the distribution of product.
2. The development of a mutual international recognition for the licensing wholesales, pharmacists and pharmacies located in Canada and the United States.
3. The development of Memoranda of Understanding regarding which laws are enforced and enforceable for the safety and benefit of the patient, as many businesses require disclaimers, agreements and powers or attorney that remove patient autonomy in order to access cheaper drugs.
4. Until such time as provincial and state regulators can openly forward and receive information and intelligence with the American Food and Drugs Administration, Health Canada and other provincial and state prescriber licensing authorities, the cross-border pharmacy sale of drugs under the authority of a prescription should be limited or temporarily suspended.

5. A review is required to identify the legal impediments and barriers of investigations, complaint investigations, jurisdictional issues, power of subpoena and collection of evidence.
6. As the international movement of drugs is based heavily upon the issue of access to cheaper drugs than professional care, the flow of medication across the international border through wholesale purchases ought to be permitted rather than, or in addition to, pharmacy distribution pursuant to a prescription.
7. As confirmed by all parties knowledgeable of this industry, the Canadian drug supply cannot provide for all American patients requiring catastrophic medication nor the cost saving needs of private or state run drug benefit programs, a plan is needed, therefore, to carve-out how the cross-border movement of drugs can initially benefit those who need it the most and, ultimately, address the needs of others.
8. The drug source needs to be confirmed and only purchases directly from licensed wholesales to pharmacies would be permitted for international sale on prescription.
9. All referral prescription programs to pharmacies and businesses located outside the country of the pharmacy of first contact must be approved by the provincial and/or state licensing authority prior to implementing the program.
10. All advertisement of pharmacies servicing another country must clearly indicate their jurisdiction of license and meet the requirements of an international licensing authority, like the American/Canadian Verified Internet Pharmacy Practice Sites (VIPPS) program, and no other pharmacy business would be allowed to advertise for the international shipment of medication or participate in that activity.

In closing, The Manitoba Pharmaceutical Association is very appreciative for the invitation to address the Task Force Committee and raise matters of critical importance. The issue of cross-border movement of legal drugs is very complex and involves and entwines professional, legal and political jurisdictions. However, the overall goal must remain clear; patient safety and product quality and safety. The M.Ph.A. looks forward to the ongoing and future opportunities to work with American federal and state agencies and organizations to achieve this goal.

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